510(k) - Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	*syngo.CT Vascular Analysis*
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 Erlangen, Germany

4. Contact Person:

Mr. Ralf Hofmann
Regulatory Affairs Specialist
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-8170
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: June 07, 2011

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Device Description and Intended Use:

syngo.CT Vascular Analysis is an image analysis software package for evaluating enhanced CT images. Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such lesion. These visualization/processing/evaluation tools allow for characterization of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

8. Substantial Equivalence:

syngo.CT Vascular Analysis software package, designed for post processing images that have been continuously acquired with computed tomography (CT) imaging systems which meet certain minimal requirements, is substantially equivalent to the following devices:

Manufacturer	Product	510(k)	Clearance date
1. Siemens AG	syngo® Inspace 4D	K043469	02/03/2005
2. Siemens AG	syngo®.x	K092519	08/27/2009
3. Siemens AG	syngo® Dual Energy with extended functionality	K083524	04/01/2009
4. TeraRecon Inc.	Aquarius Intuition Workflow Platform	K061214	05/15/2006

9. Summary of Technological Characteristics of the Principle Device as Compared with the Predicate Devices

syngo.CT Vascular Analysis is a post-processing software package which provides a combination of functionality similar to functionality provided by one or more of the predicate devices as listed below. It uses the same data for evaluation as the predicate devices and provides results in the same format as the predicate devices.

As basis for data viewing, *syngo.CT Vascular Analysis* uses basic reader and image display functionality as provided by syngo®.x. In addition to basic viewing capabilities, *syngo.CT Vascular Analysis* provides tools for visualization, analysis and reporting of vascular conditions. These tools are based on segmentation of vascular structures. Accordingly, *syngo.CT Vascular Analysis* has equivalent technological characteristics as the predicate devices. Moreover, *syngo.CT Vascular Analysis* uses current image processing algorithms, in order to provide results that are substantially equivalent to those obtained with one or more of the predicate devices.

syngo.CT Vascular Analysis	**Description**	**Comparison to predicate devices**
Basic Reading Functionality	Conventional navigation on 2D and 3D views, change of layouts, adapt window values.	Same
Manual Best Plane	Rotate MPR planes to user drawn plane.	Extended. Quick mode for manipulation of reference lines.
Manual Vessel Tracking	Manual drawing of vascular paths for curved MPR visualization.	Same
Review Marker	Functionality for setting location of a clinical finding on any view.	Same
Integrated Reporting (Reporting Tools)	Functionality for editing values of clinical findings such as location, pathology, etc.	Same
Bone Removal SE	Segmentation of osseus tissue for clear visualization of vascular structures.	Same
Bone Removal DE	Segmentation of osseus tissue for clear visualization of vascular structures based on dual energy images.	Same
Bone Removal Edit	Manual interactions for correction of bone removal results.	Same
Bone Opacity	Combined VRT visualization of vascular and osseous structures.	Same
Table Removal	Segmentation of patient table for clear VRT visualization of anatomy.	Same
Lumen evaluation	Delineation of vessel contours for vascular analysis	Same
Curved MPR (CPR) and Cross Section MPR	Visualization of vessels in curved MPR with corresponding cross sectional images.	Same
Vessel Pre-Processing and Labeling	Tracking and labeling of major body vessels in pre-processing for quick presentation in curved MPR views.	Same
Vessel Tracking	Tools for semi-automatic tracking of vascular structures.	Same
Navigate Along Vessel	Semi-automatic alignment of MPR views to local vascular anatomy with interactive navigation along vessel course.	Extended. Interactive navigation along tubular structures with alignment of MPR views.
Curved and Cross-Sectional Ranges	Creation of MPR series around and along vessel paths.	Same
Stenosis Measurement	Stenotisis values based on lumen contouring.	Same

syngo.CT Vascular Analysis	Description	Comparison to predicate devices
Angio View	Inverted MIP visualization of vessels filled with contrast agent.	Same
Calcification Removal SE	Masking of high intensity structures along vessels for true lumen visualization.	Same
Calcification Removal DE	Masking of high intensity structures along vessels based on dual energy images for true lumen visualization.	Same
DICOM compatible		Same

Siemens is of the opinion that the *syngo.CT Vascular Analysis* software package is intended for the same indications for use as the predicate devices. It does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.

10. Summary of non-clinical and/or clinical testing

syngo.CT Vascular Analysis is designed to fullfill the requirements of following standards

- IEC 60601-1-6 : 2006; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: 2008
  DICOM conformity is fully covered by syngo®.x implementations.

Non clinical tests are conducted for *syngo.CT Vascular Analysis* software package during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Siemens AG Medical Solutions
% Mr. Mr. Norbert Stuiber
Responsible Third Party Official
TÜV SÜD America
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

AUG 18 2011

Re: K112020
Trade/Device Name: syngo.CT Vascular Analysis
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 11, 2011
Received: July 14, 2011

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for use

510(k) Number (if known): K112020

Device Name: **syngo.CT Vascular Analysis**

syngo.CT Vascular Analysis is an image analysis software package for evaluating enhanced CT images.

Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such lesion.

These visualization/processing/evaluation tools allow for characterization of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112020